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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,427	04/09/2004	Deepak Jain	DAPNA6	1225

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,427	JAIN, DEEPAK	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/06; 01/30/06; 08/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's election filed 05/23/2008; IDS filed 09/29/2006; IDS filed 01/30/2006; and IDS filed 08/20/2004.

Claims 1-20 are pending.

Election/Restrictions

1. Applicant's election of Group I and specific species, claims 1-8, 11, 12, in the reply filed on 05/23/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 9, 10, 13-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 1-8, 11 and 12 are included in the prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is confusing as it recites "at least one cell growth enhancer selected from the group consisting of cell growth factors", and later the claim recites :at least one growth enhancer selected from the group consisting of cytokines, regulatory factors, angiogenic factors, and adhesion protein." Is the "growth enhancer" the same "cell growth enhancer"? or they are two different components of the composition?

Regarding claim 6, what is "at least one (?)".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,591,709 ('709) by itself, or in view of either US 5,153,174 ('174) or US 4,929,442 ('442).

> Claim 1 is directed to composition comprising:
> (A) cell growth enhancer,
> (B) stimulator to cell growth enhancer,
> (C) nutrients,
> (D) cell protector,
> (E) antioxidant,
> (F) extracellular matrix protein,
> (G) stimulator of extracellular matrix protein production,
> (H) penetration enhancer,
> (I) a biologically acceptable carrier.

US '709 teaches composition useful for wound treatment by accelerating wound healing (abstract). Examples 5-17, col.16 and 17, show that the formulation comprises (A) D-glucose, i.e. monosaccharide which reads on nutrients; (B) amino acids including alanine which reads on nutrients; (C) vitamin B_{12} and/or inositol and/or choline chloride; (D) calcium chloride; (E) cupper sulfate and/or ferric sulfate; (F) lipoic acid, i.e. fat; (G) sodium chloride, potassium chloride, sodium pyruvate; (J) adenine, i.e. nucleosides; (K) purines; (L) cellular growth factor enhancer including PDGF and TGF; (M) fats; (N) cell

growth factor including EGF and IGF; (O) insulin, i.e. cell protector; (P) gel carrier (example 1).

The reference further teaches the composition comprises collagen (extracellular matrix protein), ascorbic acid (antioxidant), and propylene glycol (hydrophilic permeation enhancer) (col.3, lines 10-15; col.4, line 67; col.5, lines 3-4, 16, 26-60; col.6, lines 8-11; col.9, lines 7-15; col.11, lines 60-63; col.13, lines 1-15; col.16, lines 11-67; col.17, lines 1-19). The formulation is used to treat burns, skin wounds caused by surgical procedures, excisions, laceration, abrasions, atopic skin or narcotic wounds (col.4, lines 47-52). The reference teaches that the amount of each component in the formulation will depend upon the type and size of the wound, but each component is included in amount effective for significantly enhancing the healing of the wound relative to traditional wound healing therapies (col.7, lines 26-30).

US '709 does not teach the same amounts of different components as claimed by applicant. The claimed amounts do not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for skin treatment as disclosed by the reference, and determine the amount of each ingredient suitable to achieve a beneficial effect, motivated by the teaching of the reference that the amount of each component in the formulation will depend upon the type and size of the wound, but each component is included in amount effective for significantly enhancing the healing of the

wound relative to traditional wound healing therapies, with reasonable expectation of having a formulation effective to treat wounds and skin lesions.

Although US '709 disclosed collagen and ascorbic acid PEG, however, the reference does not teach those agents for the claimed purpose.

US 174 teaches polymer mixture useful for managing skin, wherein the polymer mixture can optimize the benefits of each single component within the mixture in a complementary and synergistic way while visibly improving the inherent esthetic properties of such components (abstract; col.7, lines 9-14). The mixture of the polymer includes elastin, glucosaminoglycan, heparin and chondroitin, which all are extracellular matrix protein; and hyaluronan, which is stimulator to extracellular matrix protein production (col.3, line 39; col.4, lines 7-12, 25, 43-47; table at col.9 till col.11). The reference teaches the composition comprising moisturizers that are all known as penetration enhancers including fatty alcohols, surfactants, and propylene glycols (col.8, lines 26-45).

US '442 teaches a composition useful and advantageous to treat or expedite healing of human skin disorder by topical application of the composition (abstract). The composition comprising EGF, TGF, GMCSF, cell adhesion protein (stimulator of extracellular matrix protein production), glycoprotein (extracellular matrix protein), and fibronectin in physiological carrier (abstract; col.2, lines 53-60; col.5, line 48). The composition further comprising material to enhance the percutaneous transfer of the active agents through the skin that include surfactant, ethanol and glycols, such as PEG (abstract; col.3, lines 1-13; col.3, lines 8-11, 48-50). The composition comprises oleic

acid, mineral oils and salts (col.7, lines 46-64). The composition can be in the form of tape or film support for controlled release of the active materials that are embedded in a matrix to the skin (col.4, lines 65-66; col.5, lines 67-68; col.6, lines 1-12).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition comprising the ingredients disclosed by US '709, and further add the mixture of polymers disclosed by US '174, because US '174 teaches that such polymer mixture is suitable for managing the skin and can optimize the benefits of each single component within the mixture in a complementary and synergistic way while visibly improving the inherent esthetic properties of such components, with reasonable expectation of having composition comprising the ingredients disclosed by US '709 and further comprises the polymer mixture disclosed by US '174 where in the composition is suitable to treat skin conditions and meanwhile has improved esthetic properties of the composition.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition comprising the ingredients disclosed by US '709, and further add extracellular matrix proteins and growth enhancers disclosed by US '442, motivated by the teaching of US '442 that the composition comprising extracellular matrix protein and adhesion protein is useful and advantageous to treat or expedite healing of human skin disorder when applied topically, with reasonable expectation of having composition comprising the ingredients disclosed by US '709 and further having extracellular matrix proteins and adhesion protein, wherein the composition is excellent skin treating composition and method.

The composition taught by US '709 by itself or by its combination with US '174 or US '442 are expected to be suitable for the intended uses claimed by claims 11 and 12 since materials and their properties are inseparable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Isis A Ghali/
Primary Examiner, Art Unit 1611

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